REMARKS

The present application contains claims 1-85, the status of which is as follows:

(a) Claims 2, 3, 7, 12, 34, 37, 39, 46, 47, 51, 53, 73, 76, 78, 80, and 85 are as originally filed.

(b) Claims 5, 8, 10, 11, 32, 35, 36, 38, 43, 44, 49, 52, 55, 74, 77, 79, and 84 were previously presented.

(c) Claims 1, 6, 13-15, 30, 33, 40-42, 45, 50, 56-58, 72, 75, 81-83, have been currently amended.

(d) Claims 4, 9, 16-29, 31, 48, 54, 59-71, have been canceled without prejudice.

No new matter has been added. Reconsideration is respectfully requested.

The Applicant thanks Examiners Rex Holmes and George Evanisko for the courtesy of an interview with the Applicant's representative, Sanford T. Colb (Reg. No. 26,856) on August 28, 2007. Agreement was reached that independent claims 1, 30, 45, and 72 are distinguished over the art of record, assuming that claim 1 is amended as indicated on page 2 of the interview summary, and that claims 30, 45, and 72 are amended accordingly. The Examiners suggested that the Applicant consider US Patent 5,792,189 to Gray before filing this response.

In the office action discussed at the interview, independent claims 1, 30, 45, and 72 had been rejected under 35 U.S.C. 102(b), over US Patent 5,797,967 to KenKnight. During the interview, Mr. Colb noted that the pacing pulses described by KenKnight do not defibrillate the heart, as recited in the claims of the present patent application (even without amendment). Instead, KenKnight's pacing pulses prepare the heart for more

efficient and/or effective defibrillation by a defibrillation-level shock. The defibrillation-level shock described by KenKnight has a strength that exceeds the strength parameters recited in the independent claims. It is noted that Applicant continues to believe that the claims pending at the time of the interview distinguish over KenKnight.

Rejections under 35 U.S.C. 102(b) over KenKnight

Claims 1-8, 10-15, 30-53, 55-58, and 72-85 were rejected under 35 U.S.C. 102(b) as being anticipated by KenKnight (US 5,797,967). As described above, even though KenKnight does describe pacing signals which have parameters that are in common with some of the signal parameters in the claims of the present patent application, this is simply because KenKnight describes applying a series of pacing pulses to prepare the heart for more efficient and/or effective subsequent defibrillation, by a defibrillation-level shock. As noted in the first paragraph of the Summary of KenKnight:

> The invention is a single electrical therapy applied to a selected region of selected cardiac tissue, comprising the combination of two discrete therapies: pacing level therapy applied to a localized portion of a region of the selected cardiac tissue having relatively low susceptibility to defibrillation-level shock field strengths; followed by (or occurring simultaneously with) defibrillation therapy applied to portions of the tissue having regions of fibrillating myocardium over which the sub-defibrillation level shocks exert control; such regions of fibrillating myocardium are those characterized by a 1:1 phase lock of a local electrogram of any region to a stimulus artifact of that region (col. 3, lines 38-49; emphasis added).

In light of the Examiners' agreement that independent claims 1, 30, 45, and 72 with the proposed amendments are distinguished over the art of record, the Applicant respectfully submits that each of these claims, as well as the claims dependent thereon, are in condition for allowance.

US Patent 5,792,189 to Gray

The Examiners suggested that the Applicant consider US Patent 5,792,189 to Gray. In the Background of Gray, it is stated that:

> The pulse energy required for internal ventricular defibrillation with known implanted defibrillators and electrode systems ranges from about 25 joules to 40 joules. Of course, the actual energy level required may differ from patient to patient, and further depends on such factors as the type of pulse waveform and the electrode configuration employed. Currently, implantable defibrillators are being tested to also treat atrial fibrillation. The energy required to defibrillate the atrium is 0.6 to 2 joules, however, during atrial fibrillation patients are conscious and even these low energy shocks can be intolerably painful for some people. [column 2, second full paragraph]

According to the first two paragraphs of the Disclosure of the Invention, Gray describes:

> The invention comprises in one aspect a method for defibrillating a heart in fibrillation which includes the steps of: detecting fibrillation of the heart; and responsive to the detecting, applying to the fibrillating heart a repeating waveform having a dominant frequency within the range of 2 Hz - 20 Hz. Preferably, the dominant frequency is near the frequency of fibrillation of the fibrillating heart, ...
>
> In another aspect, the invention comprises a defibrillator for defibrillating a fibrillating heart. ... The defibrillator further includes means for delivering the waveform to provide electrical shock to the fibrillating heart, thereby causing defibrillation of the heart.

The first two paragraphs of column 6 of Gray state:

> To investigate the mechanism of periodic waveforms on the heart, applicants studied the transmembrane potential during long duration (1-2 seconds) sinusoidal (AC) defibrillation shocks. ... Frequencies of 1, 2, 5, 10 & 20 Hz were applied during sinus rhythm with amplitudes ranging from 6-62 volts. ...

> ... For the highest amplitude stimuli, entrainment of the ventricles was achieved for frequencies of 5, 10 & 20 Hz. ... For the 10 Hz field stimulus: 1) at high amplitudes 1:1 entrainment was observed over the entire epicardium; 2) as the strength was lowered to approximately 36 volts, 1:2 entrainment became apparent in some regions; and 3) as the strength was lowered further, the regions with the lowest voltage gradient were no longer entrained to the stimulus. Entrainment during ventricular fibrillation was also achieved including two episodes of successful defibrillation. Currently, electrical defibrillation is accomplished using short duration pulses that terminate all activity. However, our results indicate that periodic field stimulation entrains heart tissue and can result in successful defibrillation utilizing a different mechanism.

As stated by Gray, the highest amplitude stimuli yielded entrainment of the ventricles, while only partial entrainment was achieved at 36 volts, and some regions of the heart were not entrained at all as the stimulus was lowered below 36 volts. The Applicant submits that at the very least, this is a teaching by Gray against the use of a defibrillating stimulus that is lower than 36 volts. The Applicant notes that a review of Gray does not show an explicit indication of the current applied during application of these 36 volts. In order to estimate the current corresponding to the 36 volts in Gray, the Applicant turns to the Examiner's analysis of KenKnight in section 3 of the outstanding office action:

being anticipated by KenKnight (U.S. Pat. [illegible]).

3. Regarding Claims 1-8, 10-15, 30-53, 55-58, 72-85, KenKnight discloses that pacing bursts are used to control fibrillation (Col. 10, ll. 57-67; Col. 11, ll. 1-11), it is further disclosed that during pacing type stimulation 1-10 V are used (Col. 5, ll. 41-45), it is further discussed that the amperage used is 10mA and the duration of 40 pulses was about 100-140ms (Col. 10, ll. 57-67 & Col. 11, ll. 1-11). Based on the voltages, amperage, the number of shocks and the duration KenKnight discloses a method and apparatus of defibrillating a heart at a rate of 10Hz for at least 100ms (~100-140ms) while supplying total energy that is less than 1 joule having an amplitude less than 50mA and a peak power that is less than 10 W. KenKnight further discloses that the

A voltage of 1-10 V at an amperage of 10 mA corresponds (R=V/I) to an interelectrode resistance of 100-1000 ohms, including the resistance of the heart tissue. Since Gray showed that 36 volts and lower did not fully entrain the heart, this range of resistances, in turn, corresponds to a demonstration that according to the techniques taught in Gray, a current of 36-360 mA does not fully entrain the heart (I = V/R = 36 volts / 100→1000 ohms). The Applicant therefore submits that it would not have been obvious to a person of ordinary skill in the art having read Gray to use currents that are even lower than 36 mA. It is noted that the claims, as currently amended, recite applying a signal that is less than 30 mA. (The Applicant reserves the right to prosecute in the future a claim reciting, for example, applying a signal that is less than 50 mA, because it is the Applicant's opinion that the upper limit value of 1000 ohms derived from KenKnight is too high.)

Description of amendments

Claims 1, 30, 45, and 72 have been amended to explicitly recite defibrillating the heart without applying shock pulses, and to recite that the steps of applying and terminating the electrical pulses effectuate defibrillation of the heart. These amendments are supported, for example, in the second paragraph of the Summary of the Invention:

> In preferred embodiments of the present invention, an electrical shockless defibrillator comprises two or more electrodes, placed at multiple sites in or on the body of a patient, and an electrical control unit. When it is determined that fibrillation or other dangerous arrhythmic activity is occurring in the heart, the control unit administers a signal comprising one or more pulses to at least one of the electrodes, typically reducing or substantially stopping activity of the heart for the duration of pulse application. Stopping heart activity in this way interrupts the arrhythmic activity and/or fibrillation. Termination of signal application then allows the heart to resume normal beating in a synchronized state.

Additionally, claims 1 and 45 have been amended to recite defibrillation of the heart by application of a pulse having an amplitude less than 30 mA. These amendments are supported, for example, in the description of Fig. 6:

> Fig. 6 is a graph (not to scale) schematically illustrating pulses generated by control unit 90, and applied to heart 20 by one or more of electrodes 100, ... In a preferred rapid pulse application mode, control unit 90 generates a regularly-spaced series of square current pulses, injecting current through the one or more electrodes into underlying cardiac tissue, in order to generate a substantially-constant contraction of the heart muscle. ... Other parameters typically characterizing the pulses include a duty cycle between about 5 and 50%, a DC offset (I_{OFFSET}) between about –10 and +10 mA, and an amplitude (I_{RP} - I_{OFFSET}) between about –20 and +20 mA, or <u>–30 to +30 mA</u> under some conditions. An amplitude of between about 1 and 5 mA, applied for a period of 1-2 seconds, is typically sufficient. These values are cited by way of example, and it will be understood that higher or lower frequencies, amplitudes and durations may also be used, ...

In other words, a pulse current amplitude that is anywhere from -30 mA to 30 mA is described. The Applicant notes that this amendment was not made in response to a rejection, and that the Applicant entered this amendment in order to accelerate the issuance of a patent covering an embodiment which is important to the Applicant. As noted above, the Applicant reserves the right to prosecute in future applications claims which are broader than claims 1 and 45 as currently amended, and the Applicant believes that such claims are patentable.

Claims 30 and 72 have been amended to specifically recite treatment of ventricular fibrillation. These amendments are supported, for example, in the following:

> In some preferred embodiments of the present invention, at least some of the electrodes are placed at multiple sites on the epicardium and/or endocardium of the left and right ventricles. [page 3, lines 12-14 of PCT/IL00/00302]
>
> Fig. 11 schematically illustrates an electrical signal applied to a beating pig heart, in accordance with a preferred embodiment of the present invention, and experimental results obtained thereby. In this experiment, a 15 Hz, 700 millisecond, 0.5 mA peak-to-peak square wave was applied in three consecutive bursts, separated by 300 milliseconds. The first burst induced an arrhythmia which looked like ventricular fibrillation, and captured the heart. Termination of the three bursts released the heart, whereupon the arrhythmia resolved, and normal cardiac activity resumed within approximately 500 milliseconds. It is believed that application of such signals to a heart already in fibrillation will similarly resolve the fibrillation within several seconds. [page 15 of the PCT, last paragraph]
>
> By contrast to the 5 - 15 joule shocks applied during a 10 millisecond period according to conventional defibrillation techniques, the defibrillation signal utilized in this experiment delivered, per electrode, less than 10 millijoules to the heart during a period greater than 100 times as long. Because the peak rate of energy transfer to the heart during defibrillation, as provided by these embodiments of the present invention, is approximately two to five orders of magnitude smaller than that utilized in the prior art, it is believed that shockless defibrillation provided by these embodiments is substantially safer and less traumatic than prior art defibrillation techniques. It is noted that prior art defibrillation techniques are unable to safely and effectively

terminate ventricular fibrillation using shocks of significantly less than 5 - 15 joules. These techniques usually apply the energy over a period of less than 10 milliseconds. Thus, the peak rate of energy transfer to the heart associated with these techniques is typically above 500 W. Preferred embodiments of the present invention generally apply energy to the heart at a peak rate of less than about 100 W, and, as in the experiment shown in Fig. 11, can be successfully implemented using energy transfer rates significantly lower than 10 W (e.g., 10 - 100 mW). [page 16 of the PCT, first paragraph]

Claims 6, 13-15, 33, 40-42, 50, 56-58, 75, and 81-83 have been currently amended to more positively recite the respective inventions of each of the claims. No new matter has been added.

The Applicant believes the amendments and remarks presented hereinabove to be fully responsive to all of the grounds of rejection and objection raised by the Examiner. In view of these amendments and remarks, the Applicant respectfully submits that all of the claims in the present application are now in order for allowance. Notice to this effect is respectfully requested.

Respectfully submitted,

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